DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 12, 2014

Dentalpoint AG
C/O Ms. Roshana Ahmed
Regulatory Affairs Manager
OptumInsight (Canada) Inc.
4 Innovation Drive
Dundas, Ontario L9H7P3
CANADA

Re: K133255
Trade/Device Name: Zeramex® T and Zeramex Plus Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 10, 2014
Received: July 14, 2014

Dear Ms. Ahmed:

This letter corrects our substantially equivalent letter of August 12, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part, please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133255

Device Name
Zeramex® T Dental Implant System

Indications for Use *(Describe)*
The Zeramex® T Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function.

The Zeramex® T Dental Implant System can be used for single or multiple unit restorations.

Zeramex® T implants are intended for delayed loading.

The Zeramex® T dental implants are specially indicated for patients with metal allergies and chronic illnesses due to metal allergies.

The Zeramex® T (Ø 3.5 mm) implant may only be used in the anterior teeth in the lower jaw and lateral teeth in the upper jaw.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

B. 510(k) Summary

Manufacturer Name:	Dentalpoint AG
Address:	Hohlstrasse 614 Zurich, Switzerland 8048
Contact Name:	Viktor Lienhard
Title:	Sales Management
Phone Number:	(+41) 44 388 36 36
Fax Number:	(+41) 44 388 36 39
Date Prepared:	July 10, 2014

Device Proprietary Name:	Zeramex® T Dental Implant System
Device Common or Usual Name:	Dental Implant Systems
Classification Name:	Root-form Endosseous Dental Implants
Classification Code:	DZE, NHA
Regulation Number:	872.3640

Predicate Devices:

Substantial equivalence is claimed to the following devices:

Name of Device	**Manufacturer**	**510(k) Number**
CeraRoot Implant System	Oral Iceberg S.L.	K093595
Z-Look3 Dental Implant System	Z-Systems AG	K062542
Branemark System®	Nobel Biocare USA Inc.	K992937

Description of the Device

The Zeramex® T System is an endosseous dental implant/abutment system. The Zeramex® T implants are placed using the Zeramex® T surgical tools. The implants are provided in three diameters (Ø 3.5 mm, 4.2 mm, and 5.5 mm) and three lengths (8 mm, 10 mm, and 12 mm). The Ø 4.2 mm implant is also offered in a 14 mm length. Dentalpoint AG offers several compatible abutments and other accessories including straight and angular (15^{o}) abutments in small, regular/wide, and wide sizes, healing caps, and gingiva formers. The abutments are bonded to the implants using dental cements which have been tested and validated for use with the Zeramex system: Panavia (K032455) and 3M ESPE RelyX (K111185).

Class I, 510(k) exempt accessories are provided in the Zeramex® T tray and include drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication or dental prosthetics, and trial abutments. The surgical tools are intended to be reprocessed (cleaned, disinfected, and sterilized) after each procedure.

Intended Use/Indications for Use

The Zeramex® T Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function.

The Zeramex® T Dental Implant System can be used for single or multiple unit restorations.

Zeramex® T implants are intended for delayed loading.

The Zeramex® T dental implants are specially indicated for patients with metal allergies and chronic illnesses due to metal allergies.

The Zeramex® T (Ø 3.5 mm) implant may only be used in the anterior teeth in the lower jaw and lateral teeth in the upper jaw.

Technological Characteristics

Zeramex® T Dental Implant System has the same intended use as the predicate devices, with implants intended for implantation in the upper and lower jaw in order to restore aesthetics and a patient's chewing function. The two-piece, sterile implants and abutments are manufactured from zirconium oxide. An internal cylindrical connection serves as an anti-rotation feature and mechanically locks the fixtures ensuring form- and force-fit connections. The implants and abutments are provided in similar diameters and lengths as the predicate devices. Implant surfaces are treated via grit blasting and acid etching processes. The Zeramex® abutments are fixed via an adhesive process which affixes the abutment to the implant, and in conjunction with the anti-rotational feature, prevents the abutments from being removed.

A comparison of the subject and predicate devices is provided below.

	Zeramex® T Dental Implant System	CeraRoot Implant System (K093595)	Z-Look3 Dental Implant System (K062542)	Branemark System® Dental Implants (K992937)
Manufacturer	Dentalpoint AG	Oral Iceberg S.L.	Z-Systems AG	Nobel Biocare USA, Inc
Materials	Zirconia	Zirconia	Zirconia	Titanium
Implant Lengths	8 mm 10 mm 12 mm 14 mm	8 mm 10 mm 12 mm 14 mm	10 mm 11.5 mm 13 mm 14 mm	10 mm – 21 mm
Implant Diameter	3.5 mm 4.2 mm 5.5 mm	3.5 mm 4.1 mm 4.8 mm	3.25 mm 4.0 mm 5.0 mm	3.75 mm 4 mm

		6.0 mm 6.5 mm		
Design	Two-piece design	One-piece design	One-piece design	Two-piece design
Anti-Rotation Features	Internal cylindrical connection + cement	N/A	N/A	Unknown
Surface Treatment	Grit blasted, acid etched	Acid etched	Grit blasted	No surface coating
Sterilization	Steam, SAL 10^{-6}	Ethylene oxide, SAL 10^{-6}	Steam, SAL 10^{-6}	Dry heat/ Steam

Pre-Clinical Testing

Testing to support the safety and effectiveness of the devices included:

- Fatigue testing in accordance with ISO 14801
- Surface chemical analysis
- Validation of cleaning, disinfection, and sterilization processes
- Packaging and transport validation

Clinical Testing

A single-center, open-label, prospective clinical study was conducted to demonstrate the safety and effectiveness of the Zeramex® T dental implants. Partially edentulous, systemically healthy patients were enrolled in the study. A total of 49 implants spanning the range of offered diameters and lengths were placed in lower and upper jaw. The overall two-year cumulative survival rates 1 and 2 years after loading was 87%. The soft-tissue complication rate was 0%, the technical complication rate was 4%, the complication rate for bone loss greater than 2 mm was 0%, and the aesthetic complication rate was 0%.

Conclusion

The results of the non-clinical and clinical testing support that the Zeramex® T Dental Implant System is safe and effective. Although minor differences in design and technology exist between the subject and predicate devices, the testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the Zeramex® T Dental Implant System is substantially equivalent to the predicate devices.